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PATENT

Attorney Docket No.: 021819-000300US

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

On November 16, 2007

TOWNSEND and TOWNSEND and CREW LLP

By Teresa R. O'Leary

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Steven W. Dow, et al.

Application No.: 10/621,254

Filed: July 14, 2003

For: VACCINES USING PATTERN  
RECOGNITION RECEPTOR-  
LIGAND:LIPID COMPLEXES

Customer No.: 20350

Confirmation No.: 9736

Examiner: HOLLERAN, Anne L.

Art Unit: 1643

Rule 1.132 Declaration

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

1. I, Steven W. Dow, Ph.D., am a Professor at Colorado State University in Fort Collins Colorado, and one of the inventors of the subject matter disclosed and claimed in the above-referenced patent application.

2. I hold a DVM from the University of Georgia, and a Ph.D from Colorado State University. I have worked in the field of immunology for over 15 years and specifically in the field of cellular immunology and vaccinology for over 10 years. A copy of my Curriculum Vitae is attached as Exhibit A.

3. It is my understanding that the claims currently under examination, were rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 6,693,086 for which I am an inventor. This Declaration presents that I am a common inventor with the present invention and the inventor for the cited portions (described below) of the '086 patent cited against the present application. Therefore, the invention disclosed but not claimed in the '086 patent was derived from myself as an inventor of this application and is thus not an invention "by another" as defined under §103(a).

4. I declare that I am the inventor of the subject matter corresponding with claims 34-37 and column 6, lines 41-58 of the '086 patent which teaches methods for treating cancer comprising the administration of immunostimulatory nucleic acids complexed with liposomes.

5. I declare that I am the inventor of the subject matter corresponding with column 3, lines 8-25 of the '086 patent which teaches a method that can elicit a systemic, anti-tumor immune response in a mammal that results in an increase in effector cell activity and particularly natural killer cell activity and an increased production of interferon gamma.

6. I declare that I am the inventor of the subject matter corresponding with column 13, lines 14-29 of the '086 patent which teaches that the nucleic acid may be any nucleic acid, coding or non-coding, and not necessarily operatively linked to a transcription control sequence.

7. I declare that I am the inventor of the subject matter corresponding with column 13, lines 34-35 of the '086 patent which teaches the use of a recombinant nucleic acid (reads on synthetic DNA).

8. I further declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both (18 U.S.C. § 1001), and may jeopardize the validity of the patent application or any patent issuing thereon.

Date: Nov 15, 2007

By: Steven W. Dow

Steven W. Dow, Ph.D.

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**BIOGRAPHICAL SKETCH**

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Provide the following information for the key personnel and other significant contributors in the order listed  
on Form Page 2.

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NAME Steven W. Dow, DVM, Ph.D. eRA COMMONS USER NAME STEDOW1	POSITION TITLE Professor of Immunology
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EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
University of Virginia	B.A.	1978	Biology
University of Georgia	D.V.M.	1982	Veterinary Medicine
Colorado State University	M.S.	1987	Clinical Sciences
Colorado State University	Ph.D.	1992	Comparative Pathology

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**A. Professional Experience**

2007-present: Professor, Dept of Microbiology, Immunology, and Pathology and Dept of Clinical Sciences, Colorado State University, Ft. Collins, CO  
2001-2006 Associate Professor, Dept of Microbiology, Immunology, and Pathology and Dept of Clinical Sciences, Colorado State University, Ft. Collins, CO  
1995-2001 Instructor, National Jewish Medical and Research Center, Denver, CO and the University of Colorado Health Sciences Center, Denver, CO  
1993-1995 Post-Doctoral Fellow, National Jewish Medical and Research Center, Denver, CO  
1990-1993 Special Assistant Professor, Department of Pathology, Colorado State University  
1987-1990 Graduate Student, Department of Pathology, Colorado State University, Ft. Collins, CO  
1984-1987 Residency in Small Animal Medicine, Dept Clinical Sciences, Colorado State University

**Honors, Positions, and Other Professional Activities**

Magna cum laude graduate, University of Virginia (BA), 1978  
Summa cum laude graduate, University of Georgia (DVM), 1982  
Pfizer Animal Health Award for Research Excellence, Colorado State University, 2004  
Ad hoc study section member, Vaccines and Biodefense study section, National Institutes of Health, Feb. 2004  
Ad hoc study section member, Operation Bioshield, National Institutes of Health, Nov. 2004  
Ad hoc study section member, Microbiology Infectious Disease RC, National Institutes of Health, Feb. 2005  
Ad hoc study section member, Innate Host Defense IRG, National Institutes of Health, Oct. 2005  
Ad hoc study section member, Topics in Bacterial Pathogenesis, NIH, Oct. 2006; Feb, 2007  
Ad hoc study section member, Third Generation Anthrax Vaccine, NIH, Jan 2007  
Member, International and Cooperative Projects Study Section, 2007-2012  
Member, American College of Veterinary Internal Medicine  
Member, American Association of Immunologists

**B. Publications (selected, in chronological order)**

1. Dow SW, Elmslie RE, Willson AP, Roche L, Gorman C, and Potter TA. (1998). In vivo tumor transfection with superantigen plus cytokine genes induces tumor regression and prolongs survival in dogs with malignant melanoma. *J Clin Invest.* 101:2406-2414.
2. Dow SW, Liggitt DL, Fradkin L, and Potter TA. (1999) Potent activation of innate immunity induced by intravenous administration of cationic lipid-DNA complexes. *J Immunol* 163:1552-1561.
3. Dow SW, Elmslie RE, Fradkin L, Liggitt D, Willson AP, Heath TH, Potter TA. (1999). Systemic injection of DNA-lipid complexes and IL-2 or IL-12 genes controls the growth of established lung tumor metastases. *Hu Gene Ther* 10:2961-2972.
4. Dow SW, Roberts A, Orme I, and Potter TA. (2000). Immunization with f-met peptides induces immunity against *Mycobacterium tuberculosis*. *Tubercle and Lung Dis* 80:5-13.

5. Kedl R, Jordan M, Kappler J, Potter T, Marrack P, and Dow S. (2001) CD40 stimulation accelerates depletion of tumor-specific CD8+ T cells in the absence of tumor antigen vaccination. *Proc Natl Acad Sci* 98:10811-10816.
6. Higgins RJ, McKisic M, Dickinson PJ, Jimenez DF, Dow SW, Tripp LD, LeCouteur RA. (2004). Growth inhibition of an orthotopic glioblastoma in immunocompetent mice by cationic lipid-DNA complexes. *Cancer Immunol Immunother* 53:338-344.
7. Meuller, R, Veir J, Fiesler K, and Dow S. (2005) Use of immunostimulatory liposome-nucleic acid complexes in allergen specific immunotherapy of dogs with refractory atopic dermatitis - a pilot study. *Vet Dermatol* 16:61-68.
8. Dow S., Elmslie R, Kurzman I, McEwen G, Pericle F, and Liggitt D. (2005) Phase I study of liposome-nucleic acid complexes encoding the IL-2 gene for treatment of canine osteosarcoma metastases. *Hu Gene Ther* 16:937-946.
9. Sellins K, Fradkin L, Liggitt D, and Dow S. (2005). Type I interferons potently suppress gene expression following gene delivery using liposome-DNA complexes. *Mol Therapy* 12:451-459.
10. Bosio C and Dow S. (2005) Aberrant activation of pulmonary dendritic cells by *Francisella tularensis*. *J Immunol* 175:6792-6801.
11. Kamstock D, Guth A, Elmslie R, Kurzman I, Fairman J, Coro L, and Dow S. (2006) Liposome-DNA complexes infused intravenously inhibit tumor angiogenesis and elicit antitumor activity in dogs with soft tissue sarcoma. *Cancer Gene Ther* 13, 306-317.
12. Gowen B, Fairman J, Smee D, Wong M, Jung K, Pace A, Heiner M, Bailey K, Dow S., and Sidwell R. (2006) Protective immunity against acute phleboviral infection elicited through immunostimulatory cationic liposome-DNA complexes. *Antiviral Research* 69:165-172.
13. Walter C, Biller B, Lana S, Bachand A, and Dow S. (2006) Effects of chemotherapy on immune responses in dogs with cancer. *J Vet Int Med* 20:342-347.
14. U'Ren L, Kedl R, and Dow S. (2006) Immunization with liposome-DNA complexes elicits enhanced antitumor immunity. *Cancer Gene Ther* 13:1033-1044.
15. Veir J, Lappin M, and Dow S. (2006) Evaluation of a novel immunotherapy for treatment of chronic rhinitis in cats. *J Fel Med Surg*, 8: 400-411.
16. Zaks K, Jordan M, Guth A, Sellins K, Kedl R, Izzo A, Bosio C, and Dow S. (2006) Efficient immunization and cross-priming by vaccine adjuvants containing TLR3 and TLR9 agonists complexed to cationic liposomes. *J Immunol* 176:7335-7345.
17. U'Ren L, Biller B, Elmslie R, Thamm D, and Dow S. (2007). Evaluation of a novel tumor vaccine in dogs with hamangiosarcoma. *J Vet Intern Med* 21:113-120.
18. Mathes M, Jordan M, and Dow S. (2006) Evaluation of liposomal clodronate in a canine model of spontaneous autoimmune hemolytic anemia. *Expt Hematol*, 34:1393-1404.
19. McMahon RH, Williams JA, Jordan KR, Dow SW, Wilson DB, and Slansky JE. (2006) Relating MHC-Peptide, TCR affinity to immunogenicity for the rational design of tumor vaccines. *J Clin Invest* 116:2543-2551.
20. McWilliams JA, McGurran SM, Dow SW, Slansky JE, and Kedl RM. (2006) A modified tyrosinase related protein 2 epitope generates high affinity tumor-specific T cells but does not mediate therapeutic efficacy in an intradermal tumor model. *J Immunol* 177:155-161.
21. Biller B, Elmslie R, Burnett R, Avery A, and Dow S. (2007) Use of FoxP3 expression to identify regulatory T cells in healthy dogs and dogs with cancer. *Vet Immunol Immunopath*:116:69-78.
22. Lana S, U'Ren L, Elmslie R, Plaza S, and Dow S. (2007) Low-dose continuous chemotherapy for adjuvant therapy of canine hemangiosarcoma. *J Vet Intern Med* 21:764-769.
23. Kamstock D, U'Ren L, Elmslie R, Lana S, Thamm D, and Dow S. (2007) Evaluation of a xenogeneic VEGF vaccine in dogs with soft tissue sarcoma. *Cancer Immunol Immunother* 56:1299-1309.
24. Avery P, Lehman T, Hoover E, and Dow S. (2007) Sustained generation of dendritic cells from multiple tissues of cats using long-term stromal cell cultures. *Vet Immunol Immunother* 117:222-235.
25. Webb C, McCord K, and Dow S. Neutrophil function defects in dogs with sepsis. *J Vet Intern Med*, in press, 2007.
26. Webb C, Lehman T, McCord K, Avery P, and Dow S. Oxidative stress during acute FIV infection in cats. *Vet Immunol Immunopath*, in press, 2007.